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In re Application of	:
Yeadon	:
Serial No.: 10/720,050	:Decision on Petition
Filed: 19 November 2003	:
Attorney Docket No.: 1/1346	:

This letter is in response to the Petition filed under 37 C.F.R. 1.181 filed on 14 May 2008 requesting withdrawal of the restriction requirement. The delay in acting upon this petition is regretted.

BACKGROUND

This application was filed under 35 U.S.C. 111(a) and as such is subject to US restriction practice.

On 21 June 2007, the examiner mailed a restriction requirement in which the original claims 1-34 were divided into 4 groups and an election of species as to a particular dopamine D2-receptor agonsist was required. The groupings are as follows:

> Group I, a composition comprising a dopamine D2-receptor agonist and an anticholinergic according to formula 1.1.1,
> Group II, a method for treating asthma by administering the composition of Group I
> Group III, a method for treating COPD by administering the composition of Group I
> Group IV, a method for treating an obstructive airway disease by administering the composition of Group I.

On 21 August 2007, Applicants elected Group I-A, the composition comprising a dopamine D2-receptor agonist listed in claim 3a or 4 with traverse. Claims 1-4, 6-10, 20-24 and 26-34 read upon the elected invention.

On 29 October 2007, the examiner considered the traversal. The examiner withdrew claims 5 and 11-19 as being directed to non-elected inventions. Claims 1-4, 6-10, 20-34, as originally presented, were then subject to a second restriction requirement, requiring applicants to elected one of the 27 separate dopamine D2 receptor agonists recited in the alternative of claim 3 or 4, for example.

On 29 November 2007, Applicants elected Group I-A, the composition comprising a dopamine D2-receptor agonist pramipexole with traverse.

On 14 February 2008, the examiner considered the traversal and made the restriction requirement FINAL. Claims 5, 11-19, 25 and 32 were withdrawn from examination as being directed to non-elected inventions. Claims 1-4, 6-10, 20-24, 26-31, 33 and 34 were examined "to the extent they read upon the elected invention and species" and rejected as follows:

> Claims 1-4, 6-10, 20-24, 26-31, 33 and 34 were rejected under 35 U.S.C. 112 2nd paragraph.
>
> Claims 1, 2-4 (in part), 6-10, 20-22, 23-24 (in part), 26-31, 33 and 34 were rejected under 35 USC 103(a) as being unpatentable over Banerjee et al.

On 14 May 2008, applicants filed a response to the Office action and this petition to request that the Office withdraw the restriction requirement.

DISCUSSION

The petition and file history have been carefully considered.

MPEP 803 states:

> There are two criteria for a proper requirement for restriction between patentably distinct inventions:
>
> (A) The inventions must be independent (see MPEP § 802.01, § 806.06, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(j)); and
>
> (B) There would be a serious burden on the examiner if restriction is not required (see MPEP § 803.02, § 808, and § 808.02).

MPEP 806.04(f) provides the following guidance for restriction between mutually exclusive species:

> Where two or more species are claimed, a requirement for restriction to a single species may be proper if the species are mutually exclusive. Claims to different species are mutually exclusive if one claim recites limitations disclosed for a first species but not a second, while a second claim recites limitations disclosed only for the second species and

not the first. This may also be expressed by saying that to require restriction between claims limited to species, the claims must not overlap in scope.

(a) Concerning the Discrepancy between the scope of Claim 1 and the description of the Groups in the original restriction requirement.

Claim 1 is set forth below:

> 1. **(Currently Amended)** A composition comprising an active agent wherein the active agent consists of *(I)* a dopamine D2-receptor agonist, and *(II)* an anti-cholinergic agent ~~comprising a member~~ selected from the group consisting of tiotropium, ~~and~~ a pharmaceutically acceptable ~~salts~~ salt thereof, ~~anions,~~ ~~isomers~~ an isomer thereof, ~~isotopes~~ an isotope thereof, ~~polymorphs~~ a polymorph thereof, ~~hydrates~~ a hydrate thereof and ~~solvates~~ a solvate thereof, in an effective therapeutic amount to treat inflammatory disease or obstructive airways disease.

Group I was described in the original restriction requirement as

> I. **Claims 1-11, 20-34 are drawn to a composition comprising a dopamine D2-receptor agonist and an anti-cholinergic according to formula (1.1.1), classified in 514/256.**

Limiting Group I to a specific type of tioproium which is not recited in Claim 1 is improper, in view of MPEP 818 which states

> Applicant must make his or her own election; the examiner will not make the election for the applicant. 37 CFR 1.142, 37 CFR 1.143.

Group I will be examined to the extent it reads upon a anti-cholinergic agent selected from the group consisting of tiotropium, a pharmaceutically acceptable salt thereof, an isomer thereof, an isotope thereof, a polymorph thereof, a hydrate thereof, a solvate thereof. The scope of Group II/III/IV will also be corrected herein.

(b) Concerning the requirement to elect a single dopamine D2-receptor agonist

In the first restriction requirement, the examiner required applicant to elect a single species of disclosed dopamine D2-receptor agonist listed in claim 3a or 4.

3. **(Original)** The composition according to Claim 1 wherein the dopamine D2-receptor agonist is a member selected from the group consisting of:

(a) alentemol; apomorphine; biperiden; bromocriptine; cabergoline; cannoxirole; ciladopa; dopexamine; fenoldopam; ibopamine; levodopa; lisuride; methylenedioxypropylnoraporphine; naxagolide; *N*-allylnoraporphine; pergolide; pramipexole; propylnorapomorphine; protokylol; quinagolide; quinpirole; ropinirole; roxindole; talipexole; terguride; trihexyphenidyl; and trihydroxyaporphine; and salts and combinations thereof;

Applicants elected pramipexole with traverse. The petition points to the following text in MPEP 803.02 concerning election of species of dopamine D2-receptor agonists

> ...when the Markush group occurs in a claim reciting a process or a combination (not a single compound), it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is mainly responsible for their function in the claimed relationship, and it is clear from their very nature or from the prior art that all of them possess this property.

Applicants are correct that the types of claims filed in the instant application are not "improper Markush claims." The Office has not rejected the claims under 35 USC 112, second paragraph (or under any other statute) for being an improper Markush claim. However, in the Office action mailed 25 February 2008, the examiner has improperly limited the scope of the claims under examination by stating that the claims are examined insofar as they read upon the elected invention and species. This is incorrect, per MPEP 809:

> The linking claims must be examined with, and thus are considered part of, the invention elected....Where the requirement for restriction in an application is predicated upon the nonallowability of generic or other type of linking claims, applicant is entitled to retain in the application claims to the nonelected invention or inventions.

Applicants also request that the examiner extend the search and examination of the Markush claims. In response, it is noted that MPEP 803.02 sets forth guidance concerning the examination of examination required for Markush claims such as the ones filed here:

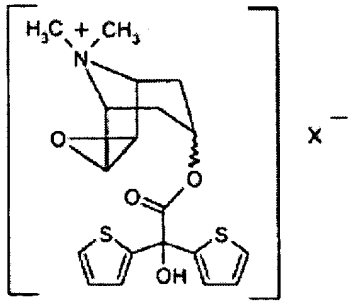
> In applications containing a Markush-type claim that encompasses at least two independent or distinct inventions, the examiner may require a provisional election of a single species prior to examination on the merits. An examiner should set forth a requirement for election of a single disclosed species in a Markush-type claim using form paragraph 8.01 when claims limited to species are present or using form paragraph 8.02 when no species claims are present. See MPEP § 808.01(a) and § 809.02(a). Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims

drawn to species patentably distinct from the elected species held withdrawn from further consideration.

(c) Concerning the restriction requirement amongst Groups II, III and IV.

In the original restriction requirement, the examiner divided the method of treatment claims up into three groups, with Claims 12-19 being placed in all three groups. Claim 12, set forth below, is broader in scope than the sum of the divisions of Groups II, III and IV, because Claim 12 encompasses treatment of inflammatory diseases other than asthma (Group II), COPD (group III) and obstructive airway diseases other than asthma or COPD (Group IV).

12. A method for the treatment of obstructive airways or other inflammatory diseases in a mammal comprising administering to the mammal a therapeutically effective amount of a composition comprising *(I)* a dopamine D2-receptor agonist and *(II)* an anti-cholinergic agent comprising a compound of Formula (1.1.1):



(1.1.1)

wherein X^- is a physiologically acceptable anion.

MPEP 806 sets forth the following general principle relating to distinctness be summarized as

(B) Where inventions are related as disclosed but are distinct as claimed, restriction may be proper.
(C) Where inventions are related as disclosed but are not distinct as claimed, restriction is never proper.

MPEP 806.03 sets forth following guidance on distinction:

Where the claims of an application define the same essential characteristics of a single disclosed embodiment of an invention, restriction therebetween should never be required. This is because the claims are not directed to distinct inventions; rather they are different definitions of the same disclosed subject matter, varying in breadth or scope of definition.

Because the sum of the groups is less than the scope of the grouped claims, the restriction amongst Groups II, III and IV is improper.

(d) Concerning the restriction requirement between product of Group I and the process of treatment (rejoined Groups II, III and IV)

MPEP 806.05(h) provides the following guidelines on establishing distinction between product and process of using.

> A product and a process of using the product can be shown to be distinct inventions if either or both of the following can be shown: (A) the process of using as claimed can be practiced with another materially different product; or (B) the product as claimed can be used in a materially different process.
>
> The burden is on the examiner to provide an example, but the example need not be documented.

In this instance, the examiner stated that the product and process of use were distinct because environmental management to avoid asthma triggers and an established drug regimen including bronchodialators may be used to treat asthma. This line of reasoning is incorrect.

MPEP 806.01 explains how one must compare the *claimed* subject matter:

> In passing upon questions of double patenting and restriction, it is the claimed subject matter that is considered and such claimed subject matter must be compared in order to determine the question of distinctness or independence.

Here, the process invention *as claimed* requires the product of Group I and does not encompass the alternatives suggested by the examiner (environmental management to avoid asthma triggers and an established drug regimen including bronchodialators). This alternative use is not viable.

MPEP 806.05(h) goes on to states that if "the applicant either proves or provides a convincing argument that the alternative use suggested by the examiner cannot be accomplished, the burden is on the examiner to support a viable alternative use or withdraw the requirement." In this instance, the product of Group I and the process of Group II/III/IV are distinct because the product *as claimed* can be used in a method which is materially different from treatment, such as in vitro product safety testing. For this reason, the restriction requirement between Group I and Groups II/III/IV is maintained.

It is noted that should all claims to the elected product invention become allowable, the examiner will reconsider rejoinder of the process claims per MPEP 821.04 and 821.04(b).

DECISION

The petition is **GRANTED-IN-PART** for the reasons set forth above.

Group I is no longer limited to the anti-cholinergic according to Formula 1.1.1. Group I is now defined as a composition comprising a dopamine D2-receptor agonist and a anti-cholinergic agent selected from the group consisting of tiotropium, a pharmaceutically acceptable salt thereof, an isomer thereof, an isotope thereof, a polymorph thereof, a hydrate thereof, a solvate thereof.

The restriction requirement amongst Groups II, III and IV is withdraw.

Group II/III/IV is no longer limited to a method of administering a composition comprising the anti-cholinergic according to Formula 1.1.1. Group II/III/IV is now defined as a method of administering a composition comprising composition comprising a dopamine D2-receptor agonist and a anti-cholinergic agent selected from the group consisting of tiotropium, a pharmaceutically acceptable salt thereof, an isomer thereof, an isotope thereof, a polymorph thereof, a hydrate thereof, a solvate thereof.

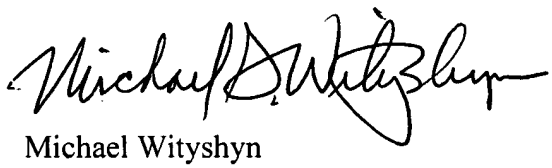
The restriction requirement among Group I and now rejoined Groups (II, III and IV) is maintained in view of the new reasons provided herein for distinction. Rejoinder between the process and product claims is premature the fact that not all claims to the elected product invention are in condition for allowance.

The indication that claims would only be examined to the extent that they read upon the elected invention and elected species has been withdrawn.

The application will be forwarded to the examiner for consideration of the papers filed 14 May 2008 and for preparation of an Office action consistent with this decision.

Any request for reconsideration must be filed within two (2) months of the mailing date of this decision.

Should there be any questions about this decision, please contact Quality Assurance Specialist Julie Burke, by letter addressed to Director, Technology Center 1600, at the address listed above, or by telephone at 571-272-1600 or by facsimile sent to the general Office facsimile number, 571-273-8300.



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